

Notice of Allowability**Application No.**

09/989,981

Examiner

Christopher J Nichols, Ph.D.

Applicant(s)

HOBBS ET AL.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 30 April 2004.
2. ☒ The allowed claim(s) is/are 1,3-7,13,14,16-21,36,37 and 72-90.
3. ☒ The drawings filed on 20 November 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 9 February 2004 has been received and entered in full.
2. The Supplemental Amendment filed 5 May 2004 has been received and entered in full.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

4. The Objection to the Specification as set forth in the previous Office Action (8 August 2003) at pp. 5 ¶10 is hereby *withdrawn* in view of Applicant's amendments (9 February 2004).
5. The Objection to the Claims as set forth in the previous Office Action (8 August 2003) at pp. 5 ¶11 is hereby *withdrawn* in view of Applicant's amendments (9 February 2004).
6. The Rejection of claims **8-12** and **36-37** under provisional obvious-type non-statutory double patenting as set forth in the previous Office Action (8 August 2003) at pp. 5-6 ¶12 is hereby *withdrawn* in view of Applicant's amendments (9 February 2004).
7. The Rejection of claims **1-21** and **36-37** under 35 U.S.C. §112 ¶1 as set forth in the previous Office Action (8 August 2003) at pp. 6-11 ¶13-23 is hereby *withdrawn* in view of Applicant's amendments (9 February 2004).
8. The Rejection of claims **1, 8, 12, and 15** under 35 U.S.C. §112 ¶1 as set forth in the previous Office Action (8 August 2003) at pp. 11-13 ¶24-29 is hereby *withdrawn* in view of Applicant's amendments (9 February 2004).

9. The Declaration of Helen Hobbs filed on 9 February 2004 and accompanying documents under 37 CFR 1.131 is sufficient to overcome the WO 02/40541 A2, WO 02/27016 A2, and WO 01/79272 A2 references. Accordingly, the Rejection of claims 1-21 and 36-37 under 35 U.S.C. §102(e) as set forth in the previous Office Action (8 August 2003) at pp. 13-15 ¶30-32 is hereby *withdrawn* in view of said Declaration and accompanying documents (9 February 2004).
10. All previously made objections and rejections not made or maintained herein are hereby *withdrawn*.

EXAMINER'S AMENDMENT

11. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the Title:

ABCG8 VECTORS, HOST CELLS, AND METHOD OF MAKING

In the Claims:

Claim 1 (Currently Amended) An isolated nucleic acid encoding an ABCG8 polypeptide, said polypeptide comprising an amino acid sequence that is at least 75% 80% identical to the full-length of an amino acid sequence as set forth in SEQ ID NO: 8, wherein said polypeptide acts to ~~effect~~ exhibits sterol transport activity.

Claim 2 (Cancelled)

Claim 3 (Previously Presented) The nucleic acid of claim 1, wherein said polypeptide comprises an amino acid sequence having 100% identity to the full length of SEQ ID NO: 8.

Claim 4 (Original) The nucleic acid of claim 1, wherein said polypeptide forms a dimer with a second ABC polypeptide, and wherein said dimer exhibits sterol transport activity.

Claim 5 (Original) The nucleic acid of claim 4, wherein said dimer is a heterodimer.

Claim 6 (Original) The nucleic acid of claim 4, wherein said sterol is cholesterol.

Claim 7 (Original) The nucleic acid of claim 5, wherein said second ABC polypeptide is an ABCG5 polypeptide.

Claims 8-12 (Cancelled)

Claim 13 (Currently Amended) The nucleic acid of claim 1, wherein said nucleic acid hybridizes under the following moderately stringent hybridization conditions:

(1) hybridization at 37°C in a hybridization buffer comprising 40% formamide, 1 M NaCl, and 1% SDS and;

(2) washing at 45°C in a wash solution comprising 1x SSC;
to a nucleic acid comprising a nucleotide sequence as set forth in SEQ ID NO: 7.

Claim 14 (Currently Amended) The nucleic acid of claim 1, wherein said nucleic acid hybridizes under the following stringent hybridization conditions:

(1) hybridization at 42°C in a hybridization buffer comprising 50% formamide, 5x SSC,
and 1% SDS and;
(2) washing at 65°C in a wash solution comprising 0.2x SSC and 0.1% SDS;
to a nucleic acid comprising a nucleotide sequence as set forth in SEQ ID NO: 7.

Claim 15 (Cancelled)

Claim 16 (Previously Presented) The nucleic acid of claim 1, wherein said nucleic acid comprises a nucleotide sequence having 100% identity to the full-length of SEQ ID NO: 7.

Claim 17 (Original) The nucleic acid of claim 1, wherein said nucleic acid is from a mouse or a human.

Claim 18 (Original) The nucleic acid of claim 1, wherein said nucleic acid is expressed in the intestine or in the liver in the presence of an LXR agonist.

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Claim 19 (Original) The nucleic acid of claim 1, wherein said nucleic acid is expressed in a tissue selected from the group consisting of liver, jejunum, ileum, and duodenum.

Claim 20 (Original) An expression cassette comprising the nucleic acid of claim 1 operably linked to promoter.

Claim 21 (Original) An isolated cell comprising the expression cassette of claim 20.

Claims 22-35 (Cancelled)

Claim 36 (Currently Amended) A method of making an ABCG8 polypeptide, the method comprising:

- (i) introducing a nucleic acid of claim 1, into a host cell or cellular extract; and
- (ii) incubating said host cell or cellular extract under conditions such that said ABCG8 polypeptide is expressed in the host cell or cellular extract.

Claim 37 (Original) The method of claim 36, further comprising recovering the ABCG8 polypeptide from the host cell or cellular extract.

Claims 38-71 (Cancelled)

Claim 72 (Previously Presented) The nucleic acid of claim 1, wherein said polypeptide is at least 85% identical to an amino acid sequence as set forth in SEQ ID NO: 8.

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Claim 73 (Previously Presented) The nucleic acid of claim 1, wherein said polypeptide is at least 90% identical to an amino acid sequence as set forth in SEQ ID NO: 8.

Claim 74 (Previously Presented) The nucleic acid of claim 1, wherein said polypeptide is at least 95% identical to an amino acid sequence as set forth in SEQ ID NO: 8.

Claim 75 (Previously Presented) The nucleic acid of claim 1, wherein said nucleic acid comprises a nucleotide sequence at least 85% identical to a sequence as set forth in SEQ ID NO: 7.

Claim 76 (Previously Presented) The nucleic acid of claim 1, wherein said nucleic acid comprises a nucleotide sequence at least 90% identical to a sequence as set forth in SEQ ID NO: 7.

Claim 77 (Previously Presented) The nucleic acid of claim 1, wherein said nucleic acid comprises a nucleotide sequence at least 95% identical to a sequence as set forth in SEQ ID NO: 7.

Claim 78 (Currently Amended) The nucleic acid of claim 1, wherein said nucleic acid comprises a conserved exon sequence selected from the group consisting of

CTGGTAGGTGAGATCTCTGACCTCCAGAGTGTTGGACTGTTGGACTGACCACTGTAG
GTGAAGTACAGACTGTTGTCACTTTCCCGAGGAGAACAAGCTTCCTGGAGGCC (bp 3-

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104 of SEQ ID NO: 9) and

CGAAGCATCCTGAAGTACAGTCCCATTCCACAGCTGGGTCTCTTCTTTGGTTTTCTC
AGCAT (bp 3436-5005 of SEQ ID NO: 9), ~~or the complementary sequence thereof.~~

Claim 79 (New) An isolated ABCG8 polypeptide, said polypeptide comprising an amino acid sequence that is at least 80% identical to the full-length of an amino acid sequence as set forth in SEQ ID NO: 8 wherein said polypeptide exhibits sterol transport activity.

Claim 80 (New) The polypeptide of claim 79, wherein said polypeptide is at least 85% identical to an amino acid sequence as set forth in SEQ ID NO: 8.

Claim 81 (New) The polypeptide of claim 79, wherein said polypeptide is at least 90% identical to an amino acid sequence as set forth in SEQ ID NO: 8.

Claim 82 (New) The polypeptide of claim 79, wherein said polypeptide is at least 95% identical to an amino acid sequence as set forth in SEQ ID NO: 8.

Claim 83 (New) The polypeptide of claim 79, wherein said polypeptide is 100% identical to an amino acid sequence as set forth in SEQ ID NO: 8.

Claim 84 (New) The polypeptide of claim 79, wherein said polypeptide forms a dimer with a second ABC polypeptide, and wherein said dimer exhibits sterol transport activity.

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Claim 85 (New) The polypeptide of claim 84, wherein said dimer is a heterodimer.

Claim 86 (New) The polypeptide of claim 84, wherein said sterol is cholesterol.

Claim 87 (New) The polypeptide of claim 85, wherein said second ABC polypeptide is an ABCG5 polypeptide.

Claim 88 (New) The polypeptide of claim 79, wherein said polypeptide is from a mouse or a human.

Claim 89 (New) The polypeptide of claim 79, wherein said polypeptide is expressed in the intestine or in the liver in the presence of an LXR agonist.

Claim 90 (New) The polypeptide of claim 79, wherein said polypeptide is expressed in a tissue selected from the group consisting of liver, jejunum ileum, and duodenum.

12. Authorization for this examiner's amendment was given in a telephone interview with Eugenia Garrett-Wachowski (Reg. No. 37,330) on 10 May 2004.

Summary

13. Claims 1, 3-7, 13-14, 16-21, 36-37, and 72-90 are hereby allowed.

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14. The Examiner acknowledges that acceptance of the amendments filed herein do not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Elizabeth C. Kemmerer

CJN
May 5, 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER